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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,032	11/20/2003	Timothy A. Geiser	ACS 58145 (3166P)	2537

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
01/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,032	GEISER ET AL.	
	Examiner	Art Unit	
	ELIZABETH HOUSTON	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-30,32-34 and 47-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30,32-34 and 47-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 26-30, 32-34, 47-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 26 and 32 include the limitation "to allow the guidewire to exit the proximal end of the guide wire receiving member and an opening formed at the proximal end of the intermediate portion of the outer catheter member *without bending*" does not find support within the disclosure of the application. Figure 1 clearly shows that the proximal portion of the guide wire lumen includes bends causing the guidewire to bend. Claim 65 explicitly states that the guide wire receiving member is "bent". Thus the guide wire does not exit the guide wire lumen and opening in the intermediate portion "without bending".

Claim Rejections - 35 USC § 103

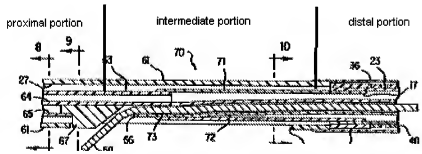
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claim 26-30, 32, 47-52, 54-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Fugoso (US 5,545,138).

2. Fischell discloses (with respect to claim 1) a catheter assembly comprising: a control handle (Fig. 1); an inner catheter (for purposes of example 23, 71, 72, 63, 11, 12) member having a proximal end and a distal end and further including a distal mounting portion (23, Fig. 7) adapted to have a medical device mounted thereon (40), the proximal end attached to the control handle, and a guide wire receiving member (72) having a proximal end and a distal end and being configured for receiving a guide wire (50, see Fig. 7), the proximal end of the guide wire receiving member being spaced apart from the proximal end of the inner catheter member (see Fig. 7 for proximal end of guidewire receiving member and see Fig. 1 for example for proximal end of inner catheter member, note that Fig. 1 is used for illustrative purposes as having the same design as Fig. 7 C7:39-43), the guide wire receiving member further including an opening at the proximal end (for example 66, fig. 7) and an opening at the distal end (for example 19, fig. 1) and a lumen extending between these openings formed on the distal and proximal ends of the guide wire receiving member; and an outer catheter member (for example 30, 32, 34, 36) co-axially disposed over the inner catheter member and dimensioned for relative axial movement relative to each other (C 5:L38-45; Fig. 3), the outer catheter member being comprised of multiple portions (see below), wherein the outer catheter member includes a distal portion having a proximal end and a distal end,

the distal portion being adapted to at least partially cover the medical device (see Figs. 1, 6, 7), the distal portion having an inner surface which directly contacts the medical device (C6:L1-4; see Fig. 1), an intermediate portion having a distal end and a proximal end, the distal end of the intermediate portion coupled to the proximal end of the distal portion, and a proximal outer member having a proximal end and a distal end, the proximal end of the proximal outer member being attached to the control handle and a the distal end of the proximal outer portion being coupled to the proximal end of the intermediate portion,



wherein the proximal end (for example 66) of the guide wire receiving member is received in an opening (for example slot 62 and the lumen associated with slot 62) formed at the proximal end of the intermediate portion of the outer catheter member.

3. With respect to claims 1 and 47, Fischell does not disclose that the proximal end of the intermediate portion has an outer diameter and the distal end of the proximal outer member has an outer diameter which is smaller than the outer diameter of the proximal end of the intermediate member to allow the guide wire to exit the proximal end of the guide wire receiving member and an opening formed at the proximal end of the intermediate portion of the outer catheter member without bending. However, Fugoso discloses a quick exchange catheter where the outer diameter of an

intermediate portion (for example between marked cross sections 2 and 3) is larger than the outer diameter of the proximal outer member (for example at marked cross section 4) to allow the guide wire to exit the guide wire receiving member and an opening on the intermediate portion without bending (see Fig. 1 and for example Fig. 5 - note middle configuration). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate this configuration into the Fischell device in order to prevent kinking and bending of the guidewire.

Claim 27, wherein the intermediate portion of the outer catheter member includes a lumen and the proximal end of the guide wire receiving member is slidably disposed within this lumen (C 5:L38-46).

Claim 28, wherein the distal mounting portion (23) of the inner catheter member has a lumen (for example 17) extending therethrough and a portion of the guide wire member extends through this lumen (See Fig. 7).

Claim 29, wherein the portion of the guide wire receiving member extending through the lumen of the distal mounting portion is secured to the wall forming the lumen (via element 71).

Claim 30 and 32 wherein the portion of the guide wire receiving member (proximal portion) which does not extend through the lumen of the distal mounting portion is slidably disposed within the lumen (27) of the intermediate portion of the outer catheter member (C5:L38-46).

Claim 48 and 58: the proximal end of the guide wire receiving member has an opening (for example 66) to the lumen of the guide wire receiving member and the proximal end

of the guide wire receiving member extends into and aligns with the passage (lumen created by slot 62) formed on the outer catheter member.

Claim 49 and 50: the distal mounting portion (23) of the inner catheter member has a lumen (for example 17) extending therethrough and a portion of the guide wire member extends through this lumen (See Fig. 7).

Claim 51: the inner catheter member includes a proximal portion (71 and 63 Fig. 7 and 11, 12 Fig. 1 of Fischell) having a proximal end and a distal end, the distal end of the proximal portion being coupled to the tubular member of the distal mounting portion (Fig.1 of Fugoso).

Claim 52: the proximal portion of the inner catheter member is an elongate component.

Claims 54, 55, 56, 57, 59, 60: the portion of the guide wire receiving member (proximal portion) which does not extend through the lumen of the distal mounting portion is slidably disposed within the lumen (27) of the intermediate portion of the outer catheter member (C5:L38-46).

Claim 61: the distal end of the proximal portion extends into and is attached within the lumen of the intermediate portion of the outer catheter member (see Fig. 1 of Fugoso).

Claim 62: The entire length of the proximal portion of the outer catheter has a smaller diameter than the intermediate portion (see Fig. 1 of Fugoso).

4. Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view of Fugoso (US 5,545,138) as applied above and further in view of McIntoish (US 2003/0028235).

Modified Fischell discloses the elements stated above except for the distal end of the proximal portion having a tapered diameter. However McIntosh teaches with respect to claim 63, a rapid exchange stent delivery device with the proximal end (near handle 28) having a tapered diameter (see where narrow diameter tapers to larger diameter). Claim 64: the tapered portion of the proximal portion and the proximal end of the intermediate portion cooperate to form the passage for the guide wire (see where passage near 64 is located where the proximal portion and the intermediate portion meet). Claim 65, the proximal end of the guide wire receiving member is bent to fit within the passage formed on the outer catheter member (see for example Fischell near element 72, Fig. 7). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a tapered portion in order to lower the profile of the length of the catheter and to provide an easy to manipulate handle for the user.

5. Claims 33, 34 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell (USPN 5,792,144) in view Fugoso (US 5,545,138) as applied above and further in view of Cummings (USPN 6,736,839).

6. Fischell discloses the invention substantially as claimed as stated above except for the proximal portion being formed from a hypotube. However, Cummings discloses a stent delivery device incorporating a sheath where in a hypotube is the proximal portion of the sheath or outer member (Col 3, line 60-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hypotube into the proximal portion of the device disclosed by Fischell since it is well known in the art

to use hypotubes for increased strength and pushability. It is well known in the art that hypotubes are made form stainless steel or nickel-titanium. With the incorporation of a hypotube, the proximal portion will inherently be less flexible than the intermediate portion.

Response to Arguments

Applicant's arguments with respect to claims 26-30, 32-34, 47-65 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
1/18/10